

REMARKS

The Applicants acknowledge the Examiner's comprehensive Office Action with appreciation. The Office maintains the previously issued Restriction Requirement with respect to the election of a single disclosed compound; however, the requirement for election of a single disclosed disorder has been withdrawn. Claims 1-16 remain pending in the application; however, Claims 6 and 7 have been withdrawn from consideration as a result of the Restriction Requirement. The Office raises rejections under 35 USC § 112, first and second paragraphs, as well as a rejection under 35 USC § 102. The Office also raises objections as to form.

Claims 1-5 and 8-16 are rejected for lack of enablement under 35 USC § 112, first paragraph. It is the position of the Office that the specification does not reasonably provide enablement for *preventing* a disorder resulting from hyperphosphorylation of microtubule protein *tau*. It is the further position of the Office that the specification, while being enabling for compounds of formula I, does not reasonably provide enablement for any aminocyclohexane or aminoalkylcyclohexane.

With the instant Amendment the term "preventing" has been deleted from the claims, and the claims have also been amended to recite specific disease states. Support for the specific disease states recited in the amended claims may be found in the instant specification at pages 20-21 as well as in originally filed Claims 9 and 10. Moreover, the aminocyclohexanes recited in the claimed method have been limited to those compounds of formula I which encompass the elected species, which compounds are acknowledged as enabled by the Office. Thus, the Applicants respectfully submit that the instantly claimed method is enabled with respect to the conditions claimed to be treatable as well as the scope of compounds recited. Reconsideration and withdrawal of the enablement rejections under 35 USC § 112, first paragraph, is respectfully requested.

Claims 1-5 and 8 are rejected for indefiniteness under 35 USC § 112, second paragraph. It is the position of the Office that the meaning of the language used to describe the claimed subject matter, i.e., "a state, disorder or condition resulting

from hyperphosphorylation of microtubule protein *tau*" and "a clinical symptom or parameter of a state, disorder or condition resulting from hyperphosphorylation of microtubule protein *tau*", is not clear. It is also the position of the Office that the limitation "the disease" recited in Claim 1 lacks sufficient antecedent basis.

As noted above with respect to the lack of enablement rejection, the claims have been amended to recite specific disease states. Thus, the language which is the basis of the indefiniteness rejections has been deleted, thereby obviating these rejections. Reconsideration and withdrawal of the indefiniteness rejections under 35 USC § 112, second paragraph, is respectfully requested.

Claims 1-5 and 8-16 are rejected under 35 USC § 102(b) as being anticipated by Shapiro (US Patent No. 5,668,117). It is the position of the Office that Shapiro discloses treating neurological diseases, such a Parkinson's disease, with memantine, and that, although the cited reference does not disclose the instantly claimed mechanism of action, the reference discloses the same active agent for the treatment of the same conditions.

Shapiro discloses that NMDA receptor antagonists, including memantine, may be used to treat neurological diseases, such as Parkinson's disease, Huntington's disease, amyotrophic lateral sclerosis, olivoponto cerebellar atrophy, and Alzheimer's disease. The Shapiro disclosure attributes the therapeutic action of memantine to its activity at the NMDA receptor.

The Applicants respectfully submit that the instant claims, as amended, do not encompass treatment of the conditions disclosed in the Shapiro reference. Moreover, treatment of instantly claimed conditions may be correlated with the ability of the instant compounds to inhibit abnormal hyperphosphorylation of microtubule protein *tau*. One skilled in the art would not have predicted such activity based on the disclosure of memantine as an NMDA receptor antagonist. Thus, the Applicants respectfully submit that the method as instantly claimed is not anticipated nor rendered obvious by the disclosure of the cited reference.

Reconsideration and withdrawal of the anticipation rejection under 35 USC § 102(b) is respectfully requested.

Finally, with the instant Amendment, the Applicants have cancelled the non-elected subject matter without prejudice to its prosecution in a Divisional Application.

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Accordingly, entry of present amendment, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned attorney has made an earnest effort to place this application into condition for immediate allowance. If he can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call him at his below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

By:



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Enclosure: Listing of Claims and Postal Card Receipt

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THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY FURTHER OR ADDITIONAL FEES WHICH MAY BE REQUIRED (DUE TO OMISSION, DEFICIENCY, OR OTHERWISE), OR TO CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 08,3220.